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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/067,800	02/08/2002	Viktor Roschke	1488.115000I	8493

28730 7590 11/02/2004

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WASHINGTON, DC 20005

EXAMINER

TURNER, SHARON L

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 11/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/067,800

Applicant(s)

ROSCHKE ET AL.

Examiner

Sharon L. Turner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-60 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Election/Restriction

1. Claims 1-60 are pending.

Improper Markush

2. Prior to setting forth the restriction requirement, it is pointed out that applicants have presented instant claims in improper Markush format, see *Ex parte Markush*, 1925 C.D. 126, *In re Weber*, 198 USPQ 334 and MPEP 803.02 and 806.04. The claims are improperly set forth as the genus claims encompassing multiple products, as identified and claimed, fail to share the characteristics of a genus, i.e., a common utility and a substantial structural feature essential to the disclosed utility. Alternatively, the claims define multiple structurally distinct compounds capable of different use, with different modes of operation, different function and different effects. A reference against one of the claimed components or methods would not be a reference against the other.

Therefore, the restriction will be set forth for each of the various groups, irrespective of the improper format of the claims, because the claims define inventions which are not proper species.

3. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-19, and 28-29 in part drawn to a polynucleotides, classified for example in class 536, subclass 23.1.
 - II. Claims 20-27, 30-50, 59-60 in part drawn to an antibody and hybridoma, classified for example in class 530, subclass 387.1.
 - III. Claims 51-56 in part drawn to a method of treating, preventing or ameliorating, classified for example in class 524, subclass 130.1.

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IV. Claims 57-58 in part drawn to a method of detecting via assaying expression of GPCR CCR5, classified for example in class 435, subclass 7.1.

4. The inventions are distinct, each from the other because of the following reasons:

5. Inventions I-II are related as products. The products are distinct each from the other as the products are comprised of divergent structure, effects and function, for example nucleic acids and antibodies each differing in nucleic and amino acid sequence.

6. Inventions III-IV are related as processes. The processes are distinct each from the other as the processes differ in reagents, steps, functions and effects. The different methods alternatively use nucleic acids, peptides, antibodies, organic and inorganic agents. Moreover each of the methods differs in contacting and assessment steps, for example binding, activity, modulation of disease, and induction of second messenger systems.

7. Inventions (I-II) and (III-IV) are related as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the processes for using the products as claimed can be practiced with another materially different product or (2) the products as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process for using the nucleic acids, peptides, antibodies, organic and inorganic compounds can be practiced with alternative nucleic acids, peptides, antibodies, organic and inorganic compounds (as further evidenced by the claims) and the products as claimed can be used alternatively in various methods (as further evidenced

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by the claims) including, a method of treatment, a method of making antibodies, a method of screening compounds, and a method for detecting compositions, a method of assessing diagnosis, modulating disease and assessing binding and activity.

8. Similar to the notations with respect to Ochiai and Brouwer noted below, claims 1-50 and 59-60 directed to distinct products link(s) inventions related to the methods of making and using the polynucleic acids and antibodies. The restriction requirement amongst the linked inventions is subject to the nonallowance of the linking claims. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. In re Ziegler, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01

9. Furthermore, in addition to the election of one of the above XVIII groups, further restriction is required under 35 U.S.C. 121 as set forth below to delineate the molecular embodiments to which the claims will be restricted in accordance with the elected group:

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A single designated nucleotide encoding VH or VL region of hybridoma selected from; (a) XF3.5F1; (b) XF1 1.1F8; (c) XF3.6A.2; (d) XF3.10B8; XF22.3C9.6; (e) XF22.9E6; (g) XF27/28.7D5; (h) XF27/28.18B5; (i) XF27/28.25G10; XF27/28.36A12; (k) XF27/28.36F11; (l) XF27/28.43E2; (m) nucleotide of N-terminal extracellular region; (n) extracellular loop 1; (o) extracellular loop 2; and (p) extracellular loop 3.

10. The inventions are distinct, each from the other because of the following reasons:

11. Although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because the products indicated constitute patentably distinct inventions for the following reasons. Each of the features, polynucleotides, encoding polypeptides and antibodies has a unique structural feature which requires a unique search of the prior art. The inventions indicated differ in structure and function as they are composed of divergent nucleic and amino acids and are differentially able to hybridize, bind and/or mediate biological functions. A reference to one element would not constitute a reference to another. In addition, searching all of the molecules in a single patent application would provide an undue search burden on the examiner and the USPTO's resources because the indicated searches are not co-extensive.

12. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

13. Because these inventions are distinct for the reasons given above and the search required for any Group is not required for any other Group, restriction for

examination purposes as indicated is proper.

14. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

15. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). In order to be fully responsive, Applicant is required to elect a single polynucleotide encoding antibody group from designated groups (a)-(p) to which the claims will be restricted, even though the requirement is traversed. Applicant is advised that neither I-III nor the noted features of (a)-(p) are species election requirements; rather each is a restriction requirements. The subject matter for examination will be restricted to the extent of the subject matter of the elected groups. No evidence is of record that any of the features share structure and/or function and each of the features and isoforms as claimed are separately useable.

16. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

17. Similarly and as noted above with respect to linking claims, the examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn

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process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04.

Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent

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issues. See MPEP § 804.01.

18. Claim 51 is generic to a plurality of disclosed patentably distinct species comprising various diseases or disorders. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species as disclosed in element (a)-(r) as designated in claim 53, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

19. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Turner, Ph.D. whose telephone number is (571) 272-0894. The examiner can normally be reached on Monday-Friday from 8:00 AM to 4:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached at (571) 272-0961.



Sharon L. Turner, Ph.D.
October 22, 2004

SHARON L. TURNER, PH.D.
PATENT EXAMINER